



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,303	01/31/2001	Larry M. Proctor	19742-001	8508

30955 7590 12/02/2003

LATHROP & GAGE LC
4845 PEARL EAST CIRCLE
SUITE 300
BOULDER, CO 80301

EXAMINER

NELSON, AMY J

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

102090 E02E/260

Office Action Summary

Application No.

90/005,892

Applicant(s)

5894079

Examiner

Amy Nelson

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 and 56-58 is/are pending in the application.
- 4a) Of the above claim(s) 16-50 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 51, 52 and 56-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15, 16, 23, 27, 30 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed 3/25/03 was in improper format. Patent Owner should refer to 37 CFR 1.173 for the proper format for making amendments in a reissue application. Furthermore, it is noted that Patent Owner has not cancelled Claims 16-50 and 53. See especially:

Claims. An amendment paper must include the entire text of each claim being changed by such amendment paper and of each claim being added by such amendment paper. For any claim changed by the amendment paper, a parenthetical expression "amended," "twice amended," etc., should follow the claim number. Each changed patent claim and each added claim must include markings pursuant to paragraph (d) of this section, except that a patent claim or added claim should be canceled by a statement canceling the claim without presentation of the text of the claim.

Changes shown by markings. Any changes relative to the patent being reissued which are made to the specification, including the claims, upon filing, or by an amendment paper in the reissue application, must include the following markings:

- (1) The matter to be omitted by reissue must be enclosed in brackets; and
- (2) The matter to be added by reissue must be underlined, except for amendments submitted on compact discs (§§ 1.96 and 1.821(c)). (emphasis added)

2. Patent Owner is advised that the original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. This requirement may be deferred until the time of allowance.

Patent Owner asserts that the requirement has been met in view of Patent Owner's offer to surrender submitted upon filing of the reissue application (response filed 3/25/03, p. 5).

Although an offer to surrender is all that is required for initiation of examination, either actual surrender of the patent, or a statement regarding its loss or inaccessibility, is required prior to allowance of the application. However, the actual surrender of the patent can be deferred until

09773303-000004

the time of allowance. *See* 37 CFR 1.178 which states that "The application may be accepted for examination in the absence of the original patent or the statement, but one or the other must be supplied before the application is allowed."

3. The drawings filed 3/25/03 are approved by the examiner.
4. The third party protests filed 3/10/03 and 4/3/03 have been considered.
5. The objections to Claims 15, 55 and 58 have been withdrawn in view of Patent Owner's amendments to the claims.
6. The rejection of Claims 7, 9, 54 and 56 under 35 U.S.C. 112, second paragraph has been withdrawn in view of Patent Owner's cancellation or amendment of the claims.
7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

8. The Information Disclosure Statements filed 2/12/02, 6/4/02, 9/27/02, and 11/26/02 have been considered, and are transmitted herewith. References that have been lined through will not be published on the face of the patent either because they are unsuitable for publication, or because important citation information, such as publication date, was missing.
9. Patent Owner is requested to file an Information Disclosure Statement listing all of the patents and references considered in the examination of the original patent.

Oath/Declaration

10. The reissue oath/declaration filed with this application is defective because it fails to identify at least one specific error that is relied upon to support the reissue application. See 37 CFR 1.175(a)(1) and MPEP § 1414. Also “sole” or “joint” inventor is omitted. Patent Owner is respectfully requested to submit a new, corrected oath.

Election/Restriction

1. Claims 16-50 and 53 are withdrawn from consideration as being directed to a non-elected invention. Although Patent Owner states in the remarks (p. 5 of the response filed 3/25/03) that Claims 16-50 and 53 have been cancelled, Patent Owner has not officially requested cancellation of those claims. Therefore, the claims are still pending.

Patent owner also traverses the restriction requirement in the response filed 3/25/03. In particular, Patent Owner states that the doctrine of constructive election is unknown to the Patent Owner (response, p. 5). Patent Owner is directed to MPEP 1450, second paragraph for an explanation of the practice.

Patent Owner further asserts that Group I – VI are related as the disclosed plants, plant characteristics and seed are capable of use together and coexist in the Enola variety. It is irrelevant that different searches are required (response, p. 5). Coexistence is not a basis for assessment of proper restriction practice. The different plants, seeds and pods are properly restricted based on their different functions and different effects, evidenced by their different characteristics. The claims are not limited to the Enola variety, but rather encompass different

groups of plants, pods or seeds, each group defined by a different characteristic or characteristics. Hence, the different plants, seeds and pods, of Groups I – IV and VI are unrelated. Moreover, the method of harvesting of Group V can be practiced with either the plants of Group I or the plants of Group II, and the pods and seeds of Groups III, IV and VI cannot be used in the method of harvesting. Finally, many of the groups have different classification, and different searches are required for each of the groups, as discussed in the restriction requirement set forth in the Official action mailed 9/25/02. Search burden is indeed a criterion for restriction.

In the instant case, restriction is proper because the different groups constitute distinct inventions, and have different classification, recognized divergent subject matter, and different required searches.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

12. Claims 1, 8, 10-13, and 51 are objected to because of the following informalities:

The phrase "Phaseolus vulgaris" should be italicized, as it is a Latin name.

Claim Rejections - 35 USC § 112

13. Claims 1-15, 51, 52, and 56-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the

reasons of record as set forth in the last Official action mailed 9/25/02. Patent Owner's arguments filed 3/25/03 have been fully considered but they are not persuasive.

Patent Owner asserts that the seeds deposited as ATCC Accession Number 209549 are not the seeds of a single genetic entity. Rather the seeds represent a variety of genetic entities, with a range of sizes, shapes and colors, both of seed coat and hilar ring. Furthermore, the plants pods and seeds display a diversity of characteristics. Patent Owner submits the Declaration of Laura L. Conley as further evidence of the genetic diversity among the deposited seeds and plants (response, p. 6, third paragraph). The Declaration discusses AFLP evidence presented as expert testimony by Paul Gepts during litigation to demonstrate the genetic diversity among individual plants of the Enola bean deposited with ATCC. In particular, individuals 1, 51, 52 and 53 are compared, and shown to differ using multiple AFLP markers (Conley Declaration filed 3/25/03, numbers 10-15, Exhibits A and B). Hence, Patent Owner asserts that the cultivar of the invention came from a variety of yellow beans, and the Examiner's statement that Patent Owner has not described other cultivars is incorrect (response, p. 7, first paragraph).

In view of Patent Owner's statements, Claims 1-7 have been included in this rejection, because Patent Owner has not provided an adequate written description of the deposited mixture of plants. However, it appears that Patent Owner has submitted conflicting evidence. The assertions made by Patent Owner appear to contradict statements made by Patent Owner in the patent disclosure. In the disclosure, Patent Owner refers to the Enola bean as a "cultivar," a term which is well understood in the art to mean a genotypically and phenotypically homogenous

population of plants. In fact, Patent Owner asserts in the disclosure that the plants were selected over numerous generations (patent specification, col. 2, line 67 – col. 3, line 29), and states that:

“The cultivar has shown uniformity and stability for all traits, as described in the Example 1, which contains a description of variety information. The cultivar has been self-pollinated a sufficient number of generations, with careful attention to uniformity of plant type to ensure phenotypic stability. The cultivar has been increased with continued observation for uniformity. No variant traits have been observed or are expected in Enola.” (patent specification, col. 4, lines 30-38).

Furthermore, the Declaration of Larry Proctor attests to the number of generations of selection, and to the uniformity and stability of the Enola cultivar (Larry Proctor Declaration filed 3/25/03, numbers 6-12). Based on the patent disclosure, it is presumed that Enola deposited as ATCC Accession Number 209549 is a bean cultivar of uniform genetic and phenotypic composition. Evidence of minor genotypic differences of a few plants using a small sample of AFLP markers is not clear evidence of a widely variant population of plants with a multitude of genetic bases for yellow seed coat color, as well as a diversity of other plant characteristics. Hence, it is submitted that Patent Owner has not satisfied the written description rejection for the broadly claimed invention.

Patent owner urges that the Examiner's application of *University of California* is misplaced, as that case was directed to written description of a genus of cDNAs based on description of a single cDNA, and does not suggest that a claimed plant genus must be supported by a sufficient number of disclosed species falling within that genus. The fact that the *University of California* case was decided before allowance of the instant patent is further evidence that the case is inapplicable (response, p. 7-8).

Examiner disagrees that the teachings of the *University of California* decision were specifically reserved for inventions related to DNA. The significance of the holding was the recognition of two distinct requirements of 112, first paragraph, the written description requirement and the enablement requirement. The holding is broadly applicable to any type of invention, and has been applied widely across the examining corps. at the United States Patent and Trademark Office. There is absolutely no basis for interpreting the *University of California* decision as being so limited. Examiner is not in a position to comment on the prior prosecution of the instant application.

Patent Owner asserts that the art of plant breeding has existed for thousands of years. Once a plant breeder is taught what heritable traits are selectable, he/she is able to replicate breeding work. The instant claims are directed to selectable traits that are all present in Enola. There is sufficient written description for those of skill in the art to replicate the results (response, p. 8, first paragraph).

The issue of reproducibility of results is one of enablement, not written description, and hence is irrelevant to the instant rejection. The issue of enablement is set forth below.

Patent Owner argues that the written description requirement is one of definiteness assuring that one skilled in the art can identify the species that the claims encompass. Here, the claimed characteristics are definite and do distinguish the claimed genus from others (response, p. 8, second paragraph).

However, it appears that Patent Owner has confused the requirements of 112, second paragraph with those of written description. Definiteness and clarity of the claimed invention are

issues of 112, second paragraph, not written description. Written description is an issue of whether there is sufficient description of the invention as to demonstrate that applicant had possession of the claimed invention at the time the application was filed. Also, Patent Owner's argument that he has distinguished the claimed genus from others is an issue of prior art, not written description. Hence, Patent Owner's arguments do not pertain to the instant 112, first paragraph rejection.

Patent Owner argues that it is in the context of enablement that the number of species usually becomes relevant, and that Examiner appears to be confusing enablement with written description (response, p. 8, last paragraph). Enablement of the invention does exist because the application teaches breeder selection criteria to replicate the claimed phenotypic traits. Patent Owner's deposit assures that plant breeders have access to germplasm for selective propagation in a wide variety of species. Even without the deposit, other breeders have been able to produce field beans in the claimed color range. Patent Owner refers to the Bassett article as evidence of independent selection of a field bean cultivar, Wagenaar, with a strong greenish yellow (SGY) seedcoat color, the same as that found in Enola. Bassett proposed a symbol "gy" for the newly discovered heritable SGY trait, which has been approved by the Genetics Committee of the Bean Improvement Cooperative (response, p. 9, first and second paragraphs).

Examiner reiterates that, as set forth in *University of California*, enablement and written description are independent requirements of 112, first paragraph. The instant rejection is a written description rejection. Patent Owner has not provided any compelling arguments for why

the written description rejection is improper, nor has Patent Owner provided evidence of possession of the invention as broadly claimed at the time of filing.

Patent Owner further asserts that the claims are sufficiently definite to permit others to identify the claimed invention. Reference to the number of species is relevant only to the claims being broader than the enabling disclosure. The specification need only teach how to make the claimed invention without undue experimentation (response, paragraph spanning p. 9-10).

Possession of the claimed invention is indicated by the evidence of Patent Owner having taught others, like Bassett, how to practice the claimed invention (response, p. 10, first and second paragraphs). The SGY trait of Bassett was not previously recognized in the art as indicated by approval of the *gy* designation (response, p. 10, first paragraph). Patent Owner refers to *Ex parte Obukowicz*, which teaches successful reversal of Examiner's rejection based on the difficulty of suitably transforming hosts, with a showing by Appellant that a number of hosts had been suitably transformed following Appellant's methodology (response, paragraph spanning p. 10-11).

Again, Patent Owner's arguments are misplaced as they are directed to issues of 112, second paragraph and enablement, and not to written description. Furthermore, Patent Owner's argument with respect to the *gy* designation is directed to prior art, not written description.

Patent Owner urges that there is no hard and fast rule about how many species must be disclosed to support a genus claim. Patent Owner cites *In re Angstadt*, *In re Metcalfe*, and *In re Vaeck* to support their assertion. The success of Bassett is evidence that undue experimentation is not required to practice the claimed invention. Bassett merely consulted the bean literature, and

embarked upon the same general type of selective breeding taught by the patent. Patent Owner cites *In re Wands* for the proposition that routine experimentation is allowable, provided it is not undue (response, p. 11-12).

The cited case law and Patent Owner's argument are all directed to issues of enablement, not written description. It is respectfully submitted that Patent Owner has not addressed the rejection of record, and therefore the rejection is maintained.

14. Claims 1-15, 51, 52, and 56-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is deemed appropriate upon further consideration, as well as in view of Patent Owner's arguments and declarations submitted 3/25/03.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The claims are broadly drawn to a *Phaseolus vulgaris* field bean plant, as well as seed, pollen and propagation material thereof, that produces seed having a seed coat that is yellow in

color, wherein the yellow color is from about 7.5 Y 8.5/4 to about 7.5 Y 8.5/6 in the Munsell Book of Color when viewed in natural light. Patent Owner further claims said plant, propagation material, pollen, and seed, wherein said seed has a hilar ring that is tan in color, wherein the tan color is from about 2.5 Y 9/4 to about 2.5 Y 9/6. And Patent Owner claims said seed which further has a smooth texture, has a pleasing taste, absorbs large volumes of water, germinates in the dark, is cuboid in shape, and has a dry seed weight of about 43 grams per 100 seeds. Patent Owner also claims a *Phaseolus vulgaris* field bean seed designated Enola, and plants and pollen thereof, deposited with the American Type Culture Collection under Accession Number 209549, as well as a method of crossing said plant with another field bean plant.

Patent Owner teaches the cultivar, Enola (seed deposited as ATTC Accession Number 209549), that has the claimed seed characteristics of yellow seed coat of from about 7.5 Y 8.5/4 to about 7.5 Y 8.5/6 in the *Munsell Book of Color* when viewed in natural light, tan hilar ring of from about 2.5 Y 9/4 to about 2.5 Y 9/6, smooth texture, pleasing taste, absorbs large volumes of water, germinates in the dark, is cuboid in shape, and has a dry seed weight of about 43 grams per 100 seeds. Patent Owner teaches that the Enola cultivar was developed as follows: yellow beans were selected from a mixed bag of dry edible beans purchased in Mexico in 1994 (col. 2, l. 63 – col. 3, l. 3); the seeds were planted and allowed to self-pollinate; plants with small leaves, good pod adherence and pod shattering resistance were selected, allowed to self-pollinate, and seeds thereof planted in 1995 (col. 3, l. 3-15); plants with good pod adherence, pod shattering resistance, and greater than average yield were selected, allowed to self-pollinate, and seeds thereof planted in 1996 (col. 3, l. 15-24); plants with good pod adherence, pod shattering

resistance, and higher yield were selected and bulked to produce the Enola cultivar (col. 3, lines 24-29). Patent Owner discloses that the Enola cultivar:

“has shown uniformity and stability for all traits, as described in Example 1, which contains a description of variety information. The cultivar has been self-pollinated a sufficient number of generations, with careful attention to uniformity of plant type to ensure phenotypic stability. The cultivar has been increased with continued observation of uniformity. No variant traits have been observed or are expected in Enola.”

Example 1 provides a detailed description of the characteristics of Enola, including plant habit, leaf morphology, flower color, pod morphology at onset and maturity, seed color, seed shape and weight, anthocyanin pigmentation, disease and stress reactions, and maturity. Patent Owner does not teach other cultivars with the claimed characteristics. Furthermore, the Declaration of Larry Proctor attests to the number of generations of selection, and to the uniformity and stability of the Enola cultivar (Larry Proctor Declaration filed 3/25/03, numbers 6-12). Based on the patent disclosure, it is presumed that Enola deposited as ATCC Accession Number 209549 is a bean cultivar of uniform genetic and phenotypic composition. Based on the patent disclosure, Examiner indicated in the prior Office action that claims directed to the deposited line were allowed.

However, in the response filed 3/25/03, Patent Owner asserts that the seeds deposited as ATCC Accession Number 209549 are not the seeds of a single genetic entity. Rather the seeds represent a variety of genetic entities, with a range of sizes, shapes and colors, both of seed coat and hilar ring. Furthermore, the plants pods and seeds display a diversity of characteristics. Patent Owner submits the Declaration of Laura L. Conley as further evidence of the genetic diversity among the deposited seeds and plants (response, p. 6, third paragraph). The Declaration

discusses AFLP evidence presented as expert testimony by Paul Gepts during litigation to demonstrate the genetic diversity among individual plants of the Enola bean deposited with ATCC. In particular, individuals 1, 51, 52 and 53 are compared, and shown to differ using multiple AFLP markers (Conley Declaration filed 3/25/03, numbers 10-15, Exhibits A and B). In view of these assertions by Patent Owner, it is submitted that the claims to the deposited ATCC Accession Number 209549 are not enabled.

The purpose of deposit of seed is to provide a reproducible means of making a genetically and phenotypically unique plant that cannot be recreated based on a patent disclosure. Hence, it has become routine in the plant breeding art to deposit seed of a genetically homogeneous line of plants, in order to obtain a plant utility patent. It is by deposit that the enablement is satisfied because it allows one of skill in the art to reproducibly make the same genetic entity. In the instant case, based on the Patent Owner's arguments filed 3/25/03 and the Conley Declaration, it appears that the seed deposited as ATCC Accession Number 209549 consist of a diverse population of genotypically and phenotypically distinct seed. Such a deposit does not enable the invention because it does not allow one of skill in the art to reproduce the same invention. Each sample of seed obtained from ATCC would consist of a different mixture of seed resulting in a different heterogenous population of plants. Therefore, Patent Owner has not enabled the invention by deposit of the seed.

However, even if the deposited seed represent a uniform, single cultivar of field bean, as indicated in the patent disclosure itself, Patent Owner has still failed to provide guidance for how to make other cultivars of field bean with the claimed characteristics of seed having a seed coat

that is yellow in color, wherein the yellow color is from about 7.5 Y 8.5/4 to about 7.5 Y 8.5/6 in the *Munsell Book of Color* when viewed in natural light, a hilar ring that is tan in color, wherein the tan color is from about 2.5 Y 9/4 to about 2.5 Y 9/6, germinates in an environment free of light, is cuboid in shape, and/or has a dry seed weight of about 43 grams per 100 seeds. Patent Owner asserts in the response filed 3/25/03 that “[P]rior to that trip [to Mexico], the applicant has never seen yellow beans, either in Mexico or the United States” (response, p. 14, fourth paragraph). Further, in response to the inquiry regarding the availability of the originally purchased seed in the United States, Patent Owner responded that “Patent Owner is not aware of any such event.” Hence, in the absence of the deposited seed, it is unclear how one of skill in the art can practice the claimed invention. Methods of plant breeding do not allow for the creation of a desired characteristic out of thin air. Hence, it would appear that without a readily available source of germplasm containing the yellow seed coat characteristic, undue trial and error experimentation would be required to screen through the myriad of *Phaseolous vulgaris* plants available in the world, and progeny plants derived therefrom, to identify other field bean plants with the claimed characteristics. It is submitted that at best Patent Owner has only provided enablement for plants of the deposited Enola line or plants produced from the deposited Enola line of Accession Number 209549.

When the *Wands* factors are weighed, given the broad scope of the claims, the lack of guidance in the specification with respect to production of plants and seeds with the claimed characteristics other than the deposited line, the statements by Patent Owner in the response filed 3/25/03 indicating that even ATCC Accession Number 209549 does not comprise a reproducible

genetically uniform field bean cultivar, and the unpredictability of plant breeding particularly when a parental source of a desired characteristic is unavailable, it is concluded that undue experimentation would be required to practice the invention, and therefore the invention is not enabled.

As discussed above, Patent Owner refers to the post-filing date Bassett Article as evidence of production of other cultivars of field bean with yellow seed coat according to the teachings of the patent. However, there is no indication that Bassett followed the teachings of the instant patent, and in fact it appears that the field bean line of Bassett was derived independently from different germplasm. Hence, Bassett does not serve as evidence of enablement of the instant invention.

15. Claims 1-7, 10 and 57 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Patent Owner regards as the invention. This rejection is in part repeated for the reasons of record as set forth in the last Official action mailed 9/25/02, and in part as a result of Patent Owner's statements and the Polly Proctor Declaration and the Conley Declaration filed 3/25/03. Patent Owner's arguments filed 3/25/03 have been fully considered but they are not persuasive.

Claim 1, and claims dependent thereon, are indefinite in view of Patent Owner's statement that:

"the seeds deposited with the ATCC are not seeds of a genetic entity. Rather, the seeds represent a variety of genetic entities with a range of sizes, shapes and colors, both seed coat and hilar ring. Furthermore, when a growout was conducted using seeds from the same source as the ATCC seeds, the plants, pods and seeds

displayed a comparable diversity of characteristics.” (response filed 3/25/03, p. 6, third paragraph).

This statement is supported by the Declaration of Polly Proctor and that of Laura L. Conley, also submitted on 3/25/03. Given the diversity of the population present in the ATCC deposit, the metes and bounds of the claimed invention are unclear. It is not apparent to the examiner how one would know whether or not one was infringing the claimed invention, given Patent Owner's failure to adequately define those seed, and plants, that are encompassed by the claims. For deposit, Patent Owner is required to deposit 2500 seeds. If those 2500 seed consist of multiple plant genotypes that are represented in differing amounts, it is not clear how one would be able to determine from a single sample of those 2500 seed which plant genotypes infringe the claimed invention, and which plant genotypes do not. In such a situation, it is also quite possible that multiple samples of the 2500 seed would reveal additional genotypes that are encompassed by the invention. Patent Owner is advised that 112, second paragraph requires Patent Owner to “clearly and distinctly” define the claimed invention. In the instant case, it is submitted that Patent Owner has not met this burden by genetic deposit of a genotypically and phenotypically divergent population of seed.

At Claim 10, the phrase “The *Phaseolus vulgaris* of claim 9” lacks proper antecedent basis. Claim 8 is directed to “A field bean variety.” The phrase should be changed to recite --The field bean variety of Claim 9--. Although Patent Owner indicates that he has responded fully to the rejection of Claim 10 (response, p. 12), it is noted that only Claim 9 has been amended. As stated in the last Official action, Patent Owner need also amend Claim 10.

At Claim 57, line 1, the phrase "said seed from the middle of a pod" lacks proper antecedent basis. It is recommended that the phrase be amended to recite --said seed is from the middle of a pod and is cuboid in shape--. Although Patent Owner indicates that appropriate amendments have been made to Claim 57 (response, p. 12), it is noted that Patent Owner has not addressed the issue of proper antecedent basis. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102/103

16. Claims 8-15, and 51, 52, and 54-58 remain rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of CIAT Accession No. G13 094 (deposited 1979; in CIAT *Phaseolus vulgaris* Catalog, 1992) or CIAT Accession No. G02 400 (deposited 1970; in CIAT *Phaseolus vulgaris* Catalog, 1992) or CIAT Accession No. G22 215 (deposited 1986; in CIAT *Phaseolus vulgaris* Catalog, 1992) or CIAT Accession No. G22 227 (deposited 1986; in CIAT *Phaseolus vulgaris* Catalog, 1992) or CIAT Accession No. 622 230 (deposited 1986; in CIAT *Phaseolus vulgaris* Catalog, 1992) or CIAT Accession No. G11 891 (deposited 1980; in CIAT *Phaseolus vulgaris* Catalog, 1992) or Kaplan (Guitarrero Cave, p. 146, 1980) or Hernandez-Xolocotzi *et al.* (Seminar Series 2E, CIAT, p. 253-258, 1973) or Voysest (Varieties of Beans in Latin America, CIAT, p. 47-50, 1983) or Gepts (The Genetic Resources of Phaseolus Beans, p. 602, 1988). This rejection is repeated for the reasons of record as set forth in the last Official action mailed 9/25/02. Patent Owner's arguments filed 3/25/03 have been fully considered but they are not persuasive.

Patent Owner asserts that the examiner has not made out a *prima facie* case of invalidity, but rather has unfairly required the patent owner to make out a *prima facie* case of validity. In particular, Patent Owner objects to the citation of textbooks which identify dozens of beans. As such, an unprecedented burden is placed on Patent Owner to locate, or attempt to locate, all of the identified beans and to demonstrate that they do not anticipate the claimed invention. The examiner can access the databases as easily as can the patent owner (response, p. 12, paragraphs 4-6).

In view of Patent Owner's broad claim to encompass all beans of *Phaseolus vulgaris* having a seed coat of a particular yellow color range, it is submitted by the examiner that it is indeed Patent Owner's burden to demonstrate that none of the prior art beans have a yellow seed coat in the claimed range. The United States Patent and Trademark Office is not equipped with facilities to evaluate the seed coat color of beans, and hence the examiner is not in a position to determine the precise color of the prior art beans that are described in a printed publication as having a yellow seed coat. The requirement of 102 is that Patent Owner be the first to invent the claimed invention. Hence, examiner need be confident that Patent Owner is the first to invent a *Phaseolus vulgaris* bean with a yellow seed coat in the claimed range in order to grant a patent to such a broad claim. Given that Patent Owner obtained beans having the yellow seed coat from a bag of seeds purchased in Mexico, and the specification does not indicate that any selection steps were made based on seed coat color, the examiner has fair reason to question the novelty of the broadly claimed invention. Patent Owner has provided no credible evidence to convince

examiner that Patent Owner has indeed discovered a novel trait that has such a rare genetic basis that it was not previously known in the prior art.

Patent Owner urges that every effort has been made to obtain beans from the six CIAT Accessions cited by the examiner, but that to date nothing has been received. Hence, Patent Owner is forced to respond to nonspecific allegations by CIAT in the request for the reexamination proceeding, which allegations were not substantiated by proper color analysis of the alleged prior art beans, and wherein CIAT has been completely uncooperative in supplying Patent Owner with samples of the beans for analysis. Patent Owner submits the Declaration of Polly Proctor filed on 3/25/03 as evidence of the multiple attempts to obtain samples of the CIAT Accessions (response, p. 13, first paragraph).

Based on the latest communications between CIAT and Ms. Proctor, as contained in the Declaration, it is apparent that samples of the CIAT Accessions were mailed on February 28, 2003 (Polly Proctor Declaration, page 57). Hence, it is presumed that by now samples of the Accessions have been received by Patent Owner, and are available for color analysis. If such is not the case, or if samples of the CIAT Accessions are not received in the near future, the examiner will reconsider the assertions of Patent Owner at that time.

Patent Owner further argues that the three beans of GRIN Accession No. PI 312090, PI 208777, and PI 282060 differ greatly from the claimed beans (response, p. 13, second paragraph). Patent Owner provides evidence in the Declaration of Polly Proctor filed 3/25/03 to indicate that the three bean lines do not produce seeds with a seed coat from about 7.5 Y 8.5/4 to

about 7.5 Y 8.5/6 in the Munsell Book of Color when viewed in natural light (Polly Proctor Declaration, p. 2, numbers 8-11).

In response to the evidence provided by Patent Owner, the rejection based on the three GRIN Accession Numbers has been withdrawn.

Patent Owner reiterates that CIAT has made it impossible for the Patent Owner to respond fully to the outstanding rejections based on the CIAT Accessions. The results based on the GRIN Accessions raise doubt as to the significance of the CIAT Accessions as prior art, and suggest that the allegations of CIAT are inequitable (response, paragraph spanning p. 13 and 14).

The merit of one prior art reference has no relevance to the merit of another prior art reference, particularly when the prior art relates to differing bean lines from differing geographic regions of the world. As stated above, it appears that the CIAT Accessions have been mailed to Patent Owner on February 28, 2003 (Polly Proctor Declaration, p. 57), and hence have by now been received by Patent Owner. Hence, Patent Owner can readily determine the relevance of the CIAT Accessions as prior art.

Patent Owner notes the efforts of Agri Sciences, Inc. to develop a yellow bean, based not on Enola, but on a "Mayacoba" bean. The newly developed bean was called "Myasi." When tested by an expert this bean was found to be indistinguishable from the Enola bean (response, p. 14, first paragraph). The Declaration of Gil Waibel submitted as part of the Declaration of Polly Proctor filed 3/25/03 indicates that the "Myasi" bean had a seed coat with a yellow color between 7.5 Y 8.5/4 and 7.5 Y 8.5/6 in the Munsell Book of Color (Polly Proctor Declaration, Exhibit D, number 42, charts 15 and 31).

Although not available as prior art, the existence of the "Myasi" bean, which is genetically distinct from Enola, but phenotypically indistinguishable with respect to seed coat color, suggests that Enola is not unique in its seed coat color characteristic. Rather, the fact that the same seed coat color can be derived from a different parental lineage suggests that the genetic basis for yellow seed coat in the claimed range is omnipresent in the germplasm of *Phaseolus vulgaris*, and in the prior art. Patent Owner is advised that it may be the unique combination of multiple characteristics that renders the Enola bean non-anticipated and non-obvious over the prior art.

Lastly, Patent Owner asserts that a *prima facie* case of obviousness has not been made by the one sentence assertion made in the rejection. If such a rejection is valid, then no botanical invention would ever be held patentable (response, p. 14, second paragraph).

Examiner notes that the instant rejection is a 102/103 rejection. The rejection clearly sets forth that due to the effects of different soils, environmental conditions, cultivation conditions and geographic conditions on the phenotypic characteristics of all plants, including beans, the claimed beans, with vaguely and/or broadly defined phenotypic characteristics, are held to be morphological variants of the prior art lines, if not anticipated by the prior art lines, in the absence of evidence to the contrary. It is unclear what aspect of the obviousness analysis Patent Owner is disputing. If Patent Owner is disputing the effect of soils, environmental conditions, cultivation conditions and geographic conditions on plant phenotype, that would be rather surprising. Much of the evidence which Patent Owner has submitted in the response filed 3/25/03 demonstrates the effects of such factors on plant phenotype. For example, Exhibit D of

the Polly Proctor Declaration explicitly discusses the effect of environment on bean phenotype.

In fact, that was the basis for choosing multiple sites for the comparison of the different bean cultivars. (Polly Proctor Declaration, Exhibit D, Preamble and Approach, p. 1-2 of the Declaration of Gil Waibel).

Information Assessment

17. A question remains as to whether or not the *Phaeseolus vulgaris* field beans purchased in Mexico were also in public use or on sale in the United States. The ability of the Office to determine whether the field beans were publicly available is limited. A search of electronic databases, the Internet and the Office's collection of retail catalogs has been conducted, however, the Office's collection of retail catalogs is not comprehensive. Furthermore, the field beans may have been sold at the wholesale level, sold under a different name, or even distributed to interested parties free of charge. Since the inventor and assignee of the instant application are in a better position to know when, if ever, the field beans were publicly available in the United States, the Examiner is requiring this information in the attached Requirement for Information Under 37 CFR 1.105.

This Office action has an attached requirement for information under 37 CFR 1.105. A complete reply to this Office action must include a complete response to the attached requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office action.

Patent Owner urges that the presumption that the Enola bean variety developed by Patent Owner did not differ in seed coat color from the originally purchased variety was incorrect.

Patent Owner submits the Declaration of Larry Proctor to clarify how the Enola bean variety was developed from the seed acquired in Mexico. Specifically, Patent Owner asserts that upon returning from Mexico, he "sorted out from the bag of beans those that had approximately yellow colored seed coats. The resultant collection varied from light to dark tan. Stated in terms of the *Munsell Book of Color*, these beans fell on various shades of the 2.5 Y page." Patent Owner, further asserts that contrary to the disclosure in the patent, Patent Owner began breeding in 1991 and completed in 1997 (response, p. 14-15). The Declaration of Larry Proctor states that the beans were acquired in June or July of 1991, that the yellow beans were separated out and were not uniform in color and shape, that between 1991 and 1995 the beans were bred through multiple generations and plants with undesirable appearances were rogued, and that each generation the seeds were more uniform in shape and color (Larry Proctor Declaration filed 3/25/03).

Patent Owner's remarks regarding development of the Enola bean variety from 1991 to 1994 are noted, however the disclosure of the patent is not changed by Patent Owner's contemporaneous assertions. Furthermore, it is unclear from Patent Owner's statement how the resultant seed, produced from sorting out of seed with yellow seed coat color, could be light to dark tan in color, or 2.5Y on the *Munsell Book of Color*, nor how Patent Owner could develop the Enola cultivar of the instant invention from seed of light to dark tan color. Clarification is requested. It is noted that Patent Owner, in the Larry Proctor Declaration, has not clarified what plants or seeds were regarded as "undesirable" and what traits were selected for, and again it is

unclear from Patent Owner's statements that plants were specifically selected based on the presence of a yellow seed coat.

Patent Owner asserts that he was not aware of the availability of the purchased beans in the United States prior to the trip to Mexico (response, p. 14, fourth paragraph). Further, Patent Owner states that he was not aware of any such event, and that he developed his invention in secrecy and filed his application less than one year prior to his first public disclosure of the invention (response, p. 15, second paragraph).

However, the question set forth by the Examiner is whether the beans purchased in Mexico were in public use or on sale in the United States prior to the filing of the instant patent application, not prior to the Patent Owner's trip to Mexico. Also, the question pertains to the beans that were purchased, not to the Enola bean variety developed by the Patent Owner. Patent Owner is again requested to supply the requested information.

Patent Owner notes that the date of sale or public use was an issue in litigation relating to Patent Owner's Plant Variety Protection Certificate. Patent Owner provides relevant documents from that litigation in an Information Disclosure Statement filed (response, p. 15, last paragraph).

Examiner has reviewed the contents of the Information Disclosure Statement filed 9/27/02, but can find no specific response to the questions raised in the 105 Request.

Page 25

The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to TC 1600 Customer Service at (703) 308-0198.

Amy Nehr

Amy J. Nelson, Ph.D.

November 25, 2003

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

[illegible]

Application Number: 09/773,303
Control Number: 90/005,892
Art Unit: 1638

Page 26

ATTACHMENT
REQUIREMENT FOR INFORMATION UNDER 37 CFR 1.105

Patent Owner and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

The information is required to determine whether, the field beans obtained in Mexico were in public use or on sale in the United States prior to the filing date of the instant patent.

In response to this requirement please provide any information available regarding the sale within the ambit of your control or that of a third party or the public use in the United States of the field bean seeds originally obtained in Mexico. Because the inventor purchased the field bean seeds in Mexico and brought them to the United States, it is reasonable to expect that Patent Owner or assignee can readily obtain information regarding the public use or sale of said seeds in the United States at the time of the original purchase and/or prior to the filing date of the instant patent.

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the Patent Owner's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

The Patent Owner is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the Patent Owner does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained will be accepted as a complete response to the requirement for that item.

This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete response to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action, which is 2 months.

09773303-0005892-1638